

CDC Smallpox Vaccine Storage and Handling Policy

This document describes policy established by the Centers for Disease Control and Prevention (CDC) regarding the storage and handling of unopened vials of Dryvax® vaccine. These recommendations help to assure state and local readiness to respond to a smallpox outbreak or to continue vaccination activities.

Storage and Handling of Unopened Vials of Smallpox Vaccine

CDC recommends that unopened vials of Dryvax® vaccine distributed for pre-event vaccination efforts continue to be maintained by state and local health agencies to assure a readiness to respond to a smallpox outbreak or to continue vaccination activities. In contrast to pediatric vaccines that are routinely returned for credit or disposal, once Dryvax® is distributed, it will not be recovered by CDC for redistribution and/or disposal.

As part of their post event smallpox plan, state and urban area BT programs have the flexibility to forward deploy local stores of Dryvax®, e.g., in local clinics or hospitals. Forward deployment must follow the policies and procedures described in the "Guidelines for Smallpox Vaccine Packing and Shipping" developed by the Strategic National Stockpile (SNS) in January 2003 (available from http://www.bt.cdc.gov/agent/smallpox/vaccination/pdf/packing-shipping.pdf). This document also describes policies and procedures regarding smallpox vaccine storage and handling (Section 2) and protecting smallpox vaccines and diluent (pages 3-5).

Two major problems in storage and handling can rapidly reduce vaccine potency: 1) freezing vaccines that should not be frozen or 2) letting infectious (live) vaccines warm. Smallpox vaccine must be kept at appropriate temperatures to retain effectiveness.

- Smallpox vaccine should be kept between 2°to 8°C (36° to 46°F).
- Smallpox vaccine, like DTaP, Hep A, Hep B, Hib, PCV and IPV, should **never** be frozen.
- Diluents should **not** be frozen.
- Smallpox vaccine should **always** be protected from heat.

Dryvax® vaccine that has been frozen should be discarded using vaccine disposal procedures noted in the following section.

Dryvax® vaccine that has been exposed to temperatures above 8°C (46°F) should be quarantined at 2°to 8°C (36° to 46°F) and not used for vaccination unless approval is provided by Drug Services, Scientific Resources Program, National Center for Infectious Diseases at CDC. Smallpox vaccination programs must contact Drug Services by calling (404) 639-3670 to receive approval for use of Dryvax® vaccine subjected to temperatures above 8°C (46°F).

August 28, 2003

Page 1 of 2

CDC Smallpox Vaccine Storage and Handling Policy

(continued from previous page)

Questions regarding the use of Dryvax® vaccine diluent in smallpox vaccine kits exposed to temperatures outside the recommended range of 2° to 8°C (36° to 46°F) should also be directed to CDC Drug Services.

Smallpox Vaccine Disposal

Unopened vials of smallpox vaccine which have been frozen, subjected to temperatures of <2°C, or >8°C and not approved for use by CDC Drug Services, or have passed expiration and/or extension dating, should be discarded using medical waste disposal procedures. Vaccine vials can be dropped into the hospital sharps container and autoclaved, or disposed of following the procedure for all other biohazard materials. These instructions are also true for empty, used smallpox vaccine vials and unused, unopened vials which have exceeded the expiration date.

In places where medical waste is buried, soaking the medical waste in a 1:10 dilution of bleach for at least 10 minutes before disposal is advised.

For more information, visit www.cdc.gov/smallpox, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

August 28, 2003

Page 2 of 2